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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,673	11/20/1998	JOHN MCCAFFERTY	28111/32106B	9420

7590

05/14/2002

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/196,673

Applicant(s)
McCafferty et al

Examiner
Padmeshri Ponnaluri

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1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/23/01; 3/5/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-145 is/are pending in the application.
- 4a) Of the above, claim(s) 66-77 and 110-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-65, 78-109, and 145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 07/971,857.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. The amendment E, filed on 7/23/01; and the amendment F, filed on 3/5/02 have been fully considered and entered into the application.
2. Claims 45-145 are currently pending in this application.
3. Claims 66-77, 110-144 withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected . Election was made **without** traverse in Paper No. 6.
4. Claims 45-65, 78-109 and 145 are currently being examined in this application.
5. The drawings filed on 11/20/98 were objected by the draftsman (see PTO 948). Applicant is invited to notice that boxes 5-6 and 12 in PTO 948 were checked by the draftsman. Applicant is encouraged to amend the specification so that the description of renumbered figure corresponds to the renumbered figures.
6. The rejection of claims 45-65, 78-109, 145 under 35 U.S.C. 112, first paragraph, for lack of written description has been withdrawn in view of applicants arguments.
7. The 35 U. S. C. . 102 (e) rejecting of claims 46, 48-49, 78-81, 86-89, 94-97 and 145 over US Patent 5,427,908 (Dower et al) has been with drawn in view of the amendments to the claims.
8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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9. Claims 46-65, 78-109 and 145 are rejected under 35 U. S. C. , 112, second paragraph, (a) for omitting essential method steps (claims 145, 45-47) set forth in the previous office action mailed on 1/18/01.

10. Claims 45-65 and 78-109 and 145 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,427,908 (Dower et al) for the reasons set forth in the previous office action mailed on 1/18/01.

11. Applicant's arguments regarding the omitting essential method steps in the independent claims, filed on 7/23/01 have been fully considered but they are not persuasive.

Applicants argue that the instant claims are drawn to a method of producing specific binding pair member, do not require the binding pair member is selected. Applicants arguments are not persuasive. The instant claims briefly recite a method of producing a specific binding pair (sbp) member, by expressing in a recombinant host cells a library of nucleic acid sequences encoding a genetically diverse population of polypeptide....., wherein said polypeptide encoded by the library are displayed at the surface of filamentous bacteriophage particles. Thus, the instant claim recites a library of recombinant host cells expressing a library of nucleic acids encoding a genetically diverse population of polypeptide. It is well known that the phage display library displays a plurality of nucleic acid sequences encoding polypeptide, however, all the sequences displayed do not encode a specific binding pair member of interest (may not bind to the ligand) . The library of nucleic acids displayed on the phage vectors are initially screened to identify a sbp which would bind to a ligand of interest. It is emphasized that all the members of the phage do

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not display nucleic acid encoding a sbp which binds to the ligand. The instant claim does not recite that the sbp member which binds to the ligand is identified in a library. Applicants are requested to amend the claims to include all the method steps.

12. Applicant's arguments regarding the obviousness rejection of claims over Dower et al, filed on 7/23/01 have been fully considered but they are not persuasive.

Applicants traverse the rejection, and argue that the amended claims recite that the instant method 'enzymes are 'non-immunoglobulin proteins' which was not in a way taught or suggested by Dower et al.

Applicants arguments have been considered, but are not persuasive. Dower et al teach general methods for screening a DNA library for a nucleotide sequence which encodes a protein of interest which has a desired binding specificity. Dower et al teach the screening methods using phase display to screen antibodies (proteins). Dower et al teach that the disclosed method of screening a DNA library for nucleotide sequence which encodes a protein of interest is typically an antibody or fragment thereof, but may also be any protein which may be cloned from a nucleotide library, and such proteins include, for example, hormones, interferon, interleukins and enzymes. Dower et al do not teach that the enzymes are non-immunoglobulin proteins. However, Dower et al teach that the disclosed screening method is applicable to screen nucleic acid library encoding a protein of interest. Dower et al teach that the nucleic acid library is cloned from hormones, interferon, interleukins and enzymes. The reference methods of screening phage display libraries readily permit the identification and isolation of phage displaying the

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specific binding pair member which specifically binds to a ligand of interest. Thus, a person skilled in the art at the time the invention was made to use the general screening method taught by Dower et al to screen a specific binding pair member which binds to an enzyme. As applicants argue in the response filed on 7/23/01 (see page 23), the techniques are equally applicable to both the antibody molecules any other displayed pair members including non-immunoglobulin proteins such as enzymes, since Dower et al teach a method of screening a DNA library for nucleotide sequence which encodes a protein of interest is typically an antibody or fragment thereof, but may also be any protein which may be cloned from a nucleotide library, and such proteins include, for example, hormones, interferon, interleukins and enzymes. The rejections of record have been maintained for the reasons of record.

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, Ph.D., can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
11 May 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER